REMARKS

Claims 1-19, 22-39, and 41-58 are pending in the present application. Claims 1, 25 and 42 have been amended. Reconsideration of the claims is respectfully requested.

I. 35 U.S.C. § 102, Anticipcation

The Examiner has rejected claims 25-28, 30, 31, 34-36 and 41 under 35 U.S.C. §102(b), as being anticipated by O'Riordan (U.S. Patent No. 5,698,090). This rejection is respectfully traversed.

In rejecting the claims, the Examiner writes:

> O'Riordan discloses a first pump (42) for receiving a first fluid through a first delivery line (22) to a catheter (10), a second (28) pump to receive a second fluid through a second delivery line (26) separate from said first delivery line, to said catheter; a processor (36) connected to control said first and second pumps; wherein the lumen of said first delivery line and the lumen of said second delivery line remain separate up to a connection point of said first and second delivery lines to said catheter. Fig. 4.

Claim 25 recites:

> 25. A clinical fluid pumping system for delivering fluids to a patient, comprising:
>
> a first delivery line for receiving a first fluid;
>
> a second delivery line for receiving a second fluid; and
>
> pumping means connected to advancing the first and second fluids through their respective said delivery lines in a known relationship to each other;
>
> wherein said first delivery line and said second delivery line are separate lumen of a single tubing, and wherein said first delivery line and said second delivery line prevent the co-mingling of the first fluid and the second fluid up to a connection point of said first and second delivery lines to a catheter that delivers fluid to a patient.

O'Riordan does not teach all of the limitations of the claimed invention and in fact teaches in the opposite direction. Rather than delivering metered fluids to a patient, O'Riordan is designed to collect fluids *from* a patient.

O'Riordan does teach or suggest first and second delivery lines that separate lumen of a single tubing, wherein the separate lumen prevent co-mingling of fluids up to a connection point to a catheter. Although the Examiner merely refers to Fig. 4, without

identifying specific structures, it is assumed the Examiner intended to references structure 10/22/26. However, upon reading the specification of O'Riordan, it is clear that these structures are not the same as those recited in claim 25. The structures 10/22/26 disclosed in Figs. 1 and 4 of O'Riordan are not delivery lines and a catheter that deliver fluids to a patient. Structure 10 is in fact a suction wand that suctions fluid from a patient:

> As illustrated in FIG. 1, blood reservoir 16 also includes vacuum port 20, inlet port 18, and outlet port 19. Inlet port 18 is connected to tubing segment 22, vacuum port 20 is connected to vacuum pump 13 through tubing segment 23, and outlet port 19 is connected to tubing segment 25 for returning collected blood to the patient or conveying it to a blood treatment device. The tip end 12 of suction wand 10 is permanently in fluid communication with vacuum pump 13, whereby fluid can be suctioned through wand 10 and tubing segment 22 into blood reservoir 16. Similarly, in the embodiment of Fig 4, the pump means includes peristaltic pump 42, directly located in tubing segment 22 for pumping fluid from suction wand 10 into blood reservoir 16. (col. 3, lines 16-30)

Moreover, tubing segments 22 and 26 are not lumen within a single tubing but rather separate tubing segments that are joined together in a "Y" configuration and are merely illustrated lying next to each other in the figures. In fact, the word "lumen" appears nowhere in O'Riordan.

Rather than preventing mixing of the two fluids, the tubing segments 22 and 26 are specifically designed to mix anticoagulant with the fluid as soon as it is collected from the patient in order facilitate proper processing of the fluid:

> Also in accordance with the invention there is provided means for introducing anticoagulant into the blood at a predetermined infusion rate. As embodied herein, the anticoagulant introducing means includes anticoagulant reservoir 24 connected to suction wand 10 via tubing segment 26. Anticoagulant reservoir 24 is typically used for holding a volume of anticoagulant such as heparin or citrate. A pump, such as a variable speed peristaltic pump 28, engages tubing segment 26 for pumping anticoagulant through tubing segment 26 and into tubing segment 22. In addition, a roller clamp 30 may be provided in tubing segment 26 to permit manual restriction of anticoagulant flow in the event of system failure. As is discussed later in greater detail, the speed of pump 28 is controlled to achieve a predetermined infusion rate for the anticoagulant.
>
> Tubing segments 22 and 26 may be joined in a "Y" configuration adjacent suction wand 10. This structure permits anticoagulant to be added

to the blood immediately as it is suctioned from a surgical cavity so that coagulation may be prevented as blood travels through tubing segment 22. (col. 3, line 51 – col. 4, line 4)

Because claims 26-28, 30, 31, 34-36 and 41 depend from claim 25, they are distinguished from O'Riordan for the reason explained above.

Therefore, it is respectfully asserted that the rejection of claims 25-28, 30, 31, 34-36 and 41 under 35 USC §102 has been overcome and should be withdrawn.

II. 35 U.S.C. § 103, Obviousness

Claims 1-4, 6-19, 22-24, 42-50 and 52-58 are rejected under 35 U.S.C. §103 as being unpatentable over Jonsson (U.S. Patent No. 5,098,372) in view of Abbot (U.S. Patent No. 5,588,816). This rejection is respectfully traversed.

In rejecting the claims, the Examiner writes:

> Jonsson discloses a first pump 910) that is configurable to pump a first metered amount of a first fluid through a first delivery line (11) to a catheter (12); a second (19) pump that is configurable to pump a second metered amount of a second fluid through a second delivery line (Fig 2) separate from said first delivery line, to said catheter, wherein the lumen of said first delivery line and the lumen of said second delivery line remain separate up to a connection point (12) of said first and second delivery lines to said catheter.
> Jonssson does not detail the controller of his device.
> Abbot teaches a processor (46) connected to control first (74) and said second (76) pumps such that said second metered amount has a definable relationship to said first metered amount (abstract)
> It would have been obvious to one ordinary [sic] skill in the art at the time the invention was made to use the controller of Abbot in order to make the device easier to use and to automatically adjust action [sic] the first and second pumps.

Jonsson does not in fact teach the limitation of the first and second delivery lines being separate lumen within a single tubing. The patient tubing 11 is separate from the line (not explicitly numbered) from reservoir 18. The word "lumen" appears nowhere in Jonsson.

Rather than delivering fluid to the patient, the patient tubing 11 is used to both draw blood from and deliver blood to the patient. The reservoir 18 delivers anticoagulant to the blood through the second tubing only when the blood is being drawn *from* the

patient:

> When drawing blood from the patient the pump 10 is operating in such a direction that it has its sucking side connected to the patient tubing 11 and its pressure side connected to the filter 14, the valve 13 being open and the valve 26 being closed. Blood is drawn from the patient/dorior and is supplied to the filter, anticoagulant solution being proportionally added to the blood from the reservoir 18 by way of the pump 19. The plasma separated from the blood in the filter 14 is collected in the plasma recipient 17 while the rest of the blood (concentrated blood) is supplied to the reservoir 15 by means of the pump 16, which is working with reduced speed as compared to the pump 10. In this working step of the procedure the position of the valve 24 is irrelevant since the valve 26 is closed.
>
> After drawing blood has been continued during a suitable period of time, working step 2 of the procedure ensues according to FIG. 2. The pumps 16 and 19 are stopped, the valve 13 is closed and the valve 26 is opened, while the valve 24 is operated periodically, alternating between the position, in which the tubing connecting container 23 and mixing container 21 is kept open and the tubing connecting reservoir 15 and the mixing container 21 is kept closed, and the opposite position, in which the tubing connecting the reservoir 15 and the mixing container 21 is open but the tubing connecting the container 23 and the mixing container 21 is pinched closed. The operating direction of the pump 10 is reversed so that the mixing container 21 is connected to the sucking side of the pump, while the tubing leading from the machine to the patient is connected to the pressure side of the pump. As a consequence of the periodic change of positions of the valve 24 the mixing container 21 will receive alternately concentrated blood and substitution fluid for administration to the patient through the patient tubing 11 and needle 12 along with the blood, now thinner from dilution with substitution fluid. The periods of keeping the valve 24 in one and the other position, respectively, need not be the same, but it is possible by control of these periods to control the degree of dilution of blood according to intentions in the case of treatment. (col. 4, line 39 – col.5, line 12)

Similar to O'Riordan, the second fluid (anticoagulant) is added to blood as soon as it is drawn from the patient to facilitate processing by the system. The second line from reservoir 18 does not deliver fluid to the patient. Instead it mixes the second fluid with the blood immediately upon the blood's collection from the patient, thereby teaching in the opposite direction of the claimed invention, which delivers two fluids to a patient through a common catheter connection and keeps them unmixed in separate lumen of a single tubing until connection with the catheter.

Therefore, even assuming for the sake of argument the Examiner's proposed

combination of Jonsson and Abbot, the resulting combination still would not produce all of the limitations recited in claims 1 and 42.

Because claims 2-4, 6-19, 22-24, 43-50 and 52-58 depend from claims 1 and 42, respectively, they are distinguished from Jonsson and Abbot for the reasons explained above.

Claims 5, 39 and 51 are rejected under 35 U.S.C. §103(a) as unpatentable over Abbot and Jonsson in view of Gillies et al. (U.S. Patent No. 6,272,370). This rejection is also respectfully traversed.

The rejection cites Gillies, saying:

> Giles [sic] et al. teaches that it is conventional in the art to utilize said receiving step receives a fluid comprising blood and said pumping step pumps adenosine.

Because claims 5, 39, and 51 depend from claims 1 and 42, respectively, they are distinguished from Jonsson, Abbot and Gillies for the reasons explained above.

Claims 29, 32, 33, 37 and 38 have been rejected under 35 USC §103 as being unpatentable over O'Riordan in view of Abbot. The rejection is traversed.

In rejecting the claims, the Examiner writes:

> O'Riordan discloses the fluid delivery system as above, but does not disclose a heat exchanger (Abbot 31) or a controller with monitoring functions (Abbot Fig 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the controller and heat exchanger of Abbot in order to more precisely control the fluid infusion.

Because claims 29, 32, 33, 37 and 38 depend from claim 25, they are distinguished from O'Riordan and Abbot for the reasons explained above.

Therefore, it is respectfully asserted that the rejection of claims 1-19, 22-24, 29, 32, 33, 37-39, and 42-58 under 35 USC §103 has been overcome and should be withdrawn.

CONCLUSION

It is respectfully urged that the subject application is patentable over the references cited by Examiner and is now in condition for allowance. Applicants request reconsideration of the application and allowance of the claims.

If there are any outstanding issues that the Examiner feels may be resolved by way of a telephone conference, the Examiner is cordially invited to contact the undersigned attorney at 972.367.2001.

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